

**Notice of Allowability**

Application No.

08/950,542

Examiner

David Lukton

Applicant(s)

BACHOVCHIN ET AL.

Art Unit

1653

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/8/03.
2. ☒ The allowed claim(s) is/are 48-55.
3. ☒ The drawings filed on 6/2/05 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)  | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)               |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. <u>1101</u> |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____               | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment                       |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance      |
|  | 9 <input type="checkbox"/> Other   |

*Christopher S. F. Low*  
**CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600**

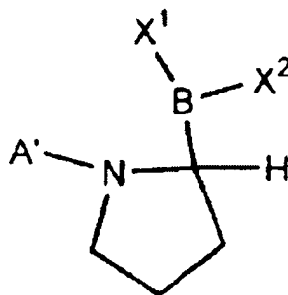
An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the Issue Fee.

- On page 1 of the specification, delete the text on lines 4-5 that pertain to the continuity status of the application and substitute therefor the following:

- - This is a continuation of application Serial No. 08/459,654, filed June 2, 1995, now abandoned, which is a divisional of application Serial No. 08/093,302, filed July 15, 1993, now U.S. Patent 5,462,928, which is a continuation of application Serial No. 07/781,552, filed October 22, 1991, now abandoned. - -

- In claim 48, line 1, delete "claim 43",  
and substitute therefor - - claim 54 - - .
- **Cancel** claims 35, 36, 39-43, 46, 47.
- **Add** the following claims:

51. A mixture of stereoisomers consisting of a compound of the following structure and at least one stereoisomer thereof:



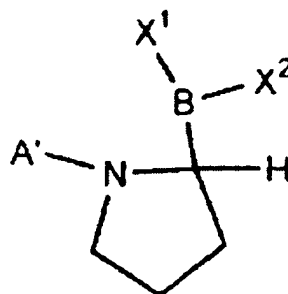
wherein each X<sup>1</sup> and X<sup>2</sup> is a hydroxyl group;

wherein at least 96% of the carbon atoms bearing boron are of the L-configuration;

wherein A' comprises an amino acid; and

wherein the compound inhibits DP-IV activity.

52. A mixture of stereoisomers consisting of a compound of the following structure and at least one stereoisomer thereof:



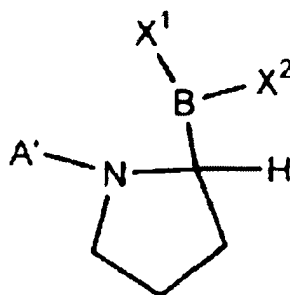
wherein each  $X^1$  and  $X^2$  is, independently, a hydroxyl group or a group that is hydrolyzed to a hydroxyl group at physiological pH;

wherein at least 99% of the carbon atoms bearing boron are of the L-configuration;

wherein A' comprises an amino acid; and

wherein the compound inhibits DP-IV activity.

53. A mixture of stereoisomers consisting of a compound of the following structure and at least one stereoisomer thereof:



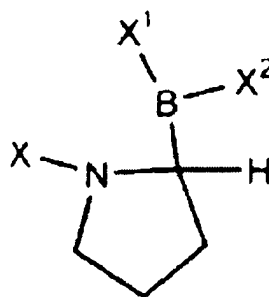
wherein each  $X^1$  and  $X^2$  is, independently, a hydroxyl group or a group that is hydrolyzed to a hydroxyl group at physiological pH;

wherein at least 96% of the carbon atoms bearing boron are of the L-configuration;

wherein A' is valine; and

wherein the compound inhibits DP-IV activity.

54. A mixture of stereoisomers consisting of a compound of the following structure and at least one stereoisomer thereof:



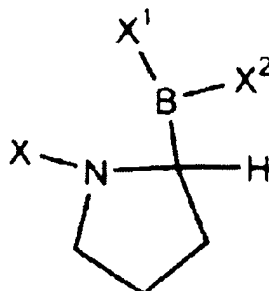
wherein each X<sup>1</sup> and X<sup>2</sup> is a hydroxyl group;

wherein at least 96% of the carbon atoms bearing boron are of the L-configuration;

wherein X comprises an amino acid or a peptide; and

wherein the compound inhibits DP-IV activity.

55. A mixture of stereoisomers consisting of a compound of the following structure and at least one stereoisomer thereof:



wherein each X<sup>1</sup> and X<sup>2</sup> is, independently, a hydroxyl group or a group that is hydrolyzed to a hydroxyl group at physiological pH;

wherein at least 99% of the carbon atoms bearing boron are of the L-configuration;

wherein X comprises an amino acid or a peptide; and

wherein the compound inhibits DP-IV activity.

Authorization for this Examiner's Amendment was given in a telephone conversation with C. Hunter Baker on 10/31/03.



The following is an Examiner's Statement of Reasons for Allowance:

The foregoing Examiner's Amendment overcomes the previously imposed §103 rejection. Each of the claims now excludes the compound disclosed in Bachovchin (*J. Biol. Chem.* **265**, 3738, 1990), or else requires a higher level of purity than was disclosed in Bachovchin. In addition, the arguments in the brief (filed 9/8/03) regarding the §112, first paragraph rejections are found persuasive.


Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably **accompany** the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."



Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
11/3/03

  
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